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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,090	06/21/2002	Stephen Arkinstall	220316USOPCT	7121

22850 7590 02/27/2009

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EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
02/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/088,090	ARKINSTALL ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2008*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *9,17,29-35,38 and 42-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9,17 and 29* is/are allowed.

6)☐ Claim(s) *30-35,38 and 42-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/4/03, 10/8/03, 9/4/08*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This is a RCE of SN 10/088,090.
Claims 1-8, 10-16, 18-28, 36-37, 39-41 have been canceled.
Claims 9, 17, 29-35, 38, 42-45 are pending.

2. Claims 30-35, 38, 42-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), where the Supreme Court looked to whether the experimentation needed to practice an invention was undue or unreasonable. *Id.* An invention must be described so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. *Id.* at 740, *Id.* at 1407. The factors to be considered herein are those set forth as the In re Wands, 8 USPQ 2nd 1400 (1988) decision.

The analysis is applied to the instant case.

Nature of invention and breadth of the claims

The claims are drawn to treating autoimmune and/or neuronal system, including epilepasy, Alzheimer's, Huntington's , Parkinson's, retinal disease, spinal cord injury, head trauma, multiple sclerosis, inflammatory bowel disease, rheumatoid arthritis, asthma, septic shock, transplant rejection, cancer, cardiovascular diseases including stroke arterosclerosis, myocardial infarction and myocardial reperfusion injury, in a human, using one of the compounds in claim 1.

The field of using a given compound in such diversity of disorder without any common etiology is incredible and highly unpredictable. The nature of the invention is highly unpredictable and the scope of the claims are extremely broad.

The state of the art, level of ordinary skill and predictability

The claimed compounds were described to have JNK down regulating/inhibiting activity. The state of the art of JNK enzyme regulation indicated that:

i) there are at least JNK1, JNK2 and JNK3 subset of the JNK enzyme. The enzyme were anatomically distributed among the diverse organs of the body (see Kumagae et al.).

ii) activity of the different subsets of JNK enzyme are structural sensitive. The conformational requirement of a compound that inhibits JNK2 (Shaw et al.) does not have any commonality with the conformational requirement of a compound that inhibits JNK3 (Scapin et al.).

iii) the claimed compounds showed no commonality with the conformational requirements for JNK2 binding compounds or JNK3 binding compounds (Shaw and Scapin supra).

iv) there is no common etiology for the diversified disorders as listed in the claims. As a matter of fact, the claims include disorder which has been known medically to be *irreversible* condition, such as myocardial infarction (see Cecil medical textbook p.247). Irreversible condition cannot be treated.

Working examples and amount of experimentation/guidance

In the specification on pages 31-39 description to various biological assays were disclosed. On page 32, data for *in vitro* binding of two compounds in a GST-JNK3 or GST-JNK2 were disclosed. The assay procedure measures the phosphorylation of biotinylated GST-c-jun protein (see p.31, line 22). A search of this material indicated there is NOTHING IN THE ART for this material (see search record exhibit I). Therefore, in absence of description of what is this material for when phosphorylated and how it can show nexus to the JNKpathway, the *in* vitro data in the specification offered mere language rather than enablement to the how to use of the compounds. The *in vitro* assay procedure, absent in any prior art, also did not offer any nexus/correlation of this method to any specific disorder from the prior art.

In view of the extreme breadth of the claims, compared to the complexity and high degree of unpredictability of the physiology for JNK pathways and the unknown nature provided in the specification to the activity of the compounds or its correlation to any specific physiology, the specification has been found to be lacking sufficient enablement disclosure for the claims.

3. Claims 9, 17 and 29 are neither anticipated or rendered obvious by the art of record (i.e. US 6,646,149) thus, are allowable.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Feb. 10, 2009

/Celia Chang/
Primary Examiner
Art Unit 1625